NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SEPRACOR INC.,	:	
Plaintiff,	:	**Hon. Dennis M. Cavanaugh**
v.	:	**OPINION**
TEVA PHARMACEUTICALS USA, INC., *et at.*	:	Civil Action No. 09-cv-01302 (DMC) (MF)
Defendants.	:	

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motion of Plaintiff Sepracor Inc. ("Plaintiff") to dismiss the affirmative defense and counterclaim of inequitable conduct asserted by Wockhardt Ltd. and Wockhardt USA LLC (collectively, "Wockhardt").

No oral argument was heard pursuant to Rule 78 of the Federal Rules of Civil Procedure. For the reasons discussed below, Plaintiff's motion to dismiss is **granted.**

I. BACKGROUND[1]

A. PROCEDURAL HISTORY

Sepracor owns U.S. Patent Nos. 6,444,673, 6,319,926, 6,864,257 and 7,318,724 (collectively, "the patents-in-suit"), which cover eszopiclone "essentially free" of its other isomer ("R-zopiclone") and methods of treating sleep-related disorders using that compound. Wockhardt, along with the

[1] The Facts in the Background Section have been taken from the parties' moving papers.

nine other groups of defendants involved in this action, have filed with the FDA Abbreviated New Drug Applications ("ANDAs") seeking approval to market generic versions of Lunesta® prior to the expiration of the patents-in-suit.

Sepracor filed an Amended Complaint against Wockhardt alleging infringement of all of the patents-in-suit on June 30, 2009. See Doc. No. 138. On July 20, 2009, Wockhardt filed an Amended Answer, which is the subject of the present motion.

Wockhardt's Amended Answer included an affirmative defense and counterclaim alleging that all of the patents-in-suit are unenforceable due to inequitable conduct.[2] In particular, Wockhardt asserts that the patent applicants improperly failed to disclose material references that would have demonstrated that the inventions do not achieve surprising and unexpected results compared with the prior art.

B. THE PATENTS

The '673 patent claims a chemical compound, namely the dextrorotatory isomer of zopiclone, and pharmaceutical compositions containing that compound. Doc. No. 140, ¶ 57. The '926 patent claims a method for improving sleep quality or time by administering the dextrorotatory isomer of zopiclone, essentially free of its levorotatory isomer, to a human. Id. The '257 patent claims a method of inducing an effect selected from the group consisting of a hypnotic effect, a sedative effect and a tranquilizing effect in a human by administering the dextrorotatory isomer of eszopiclone, essentially free of its levrorotatory isomer. Id. The '724 patent claims a mixture of isomers of [zopiclone], wherein the mixture has an optical rotation $[\alpha]_{D\ 20}$ of 135 +/- 3 when measured at 1.0

[2] Of the ten defendants in this case, only Wockhardt asserts inequitable conduct as a defense to Plaintiff's suit.

g/100 mL in acetone. Id.

Zopiclone is an organic compound. Zopiclone exists as a mixture of equal amounts of two stereoisomers. Doc. 176, at 2. A mixture of equal parts of two stereoisomers is called a racemic mixture. Id. Stereoisomers are compounds that have exactly the same set of atoms bonded to one another in exactly the same sequence, but have different three-dimensional arrangements of these atoms in space. Id. at 3. Stereoisomers which are non-superimposable mirror images of one another belong to a particular sub-class of stereoisomers known as optical isomers (or enantiomers). Id. The patents-in-suit pertain to one of the enantiomers of zopiclone. Id.

The arrangement of an optical isomer can be characterized according to the "R" or "S" classification, and/or according to the "dextrorotatory (+)" or "levorotatory (-)" classification. Id. These descriptions, however, do no necessarily correlate—i.e., a "S" isomer can be (+) or (-).

C. THE PROSECUTION HISTORY & WOCKHARDT'S INEQUITABLE CONDUCT DEFENSE

Wockhardt asserts that Plaintiff (through its employees and agents) committed inequitable conduct before the PTO in prosecuting the patents in suit. Wockhardt observes that the PTO permitted the claimed inventions to be "patent[ed] because the dextrorotatory isomer of zopiclone (also referred to as eszopiclone, the (+) isomer, or the s-isomer), possessed a surprising and unexpected property." Doc. No. 140, ¶ 52. This "unexpected property" was that the claimed dextrorotatory isomer was purportedly both more active and less toxic than the racemic mixture and levorotatory (-) isomer.

The patent applicants submitted data, declarations from scientific personnel, and attorney argument in support of the asserted "surprising and unexpected" discovery that racemic zopiclone

was more toxic than eszopiclone (the claimed compound). Id. ¶ 52. For example, the applicants made the following assertions regarding the relative toxicity of the isomers of zopiclone:

> In a racemic product, it is known that, often, one of the two enantiomers is active and that an enhancement of the toxicity may be linked to this activity, the other enantiomer being both markedly less active or inactive and less toxic. For such products, the gain in activity does not compensate for the drawbacks due to an enhanced toxicity.
>
> In the case of zopiclone, it was found, surprisingly and unexpectedly, not only that the dextrorotatory isomer is approximately twice as active as the racemate while having a lower toxicity than that of the racemate, but that the laevorotatory isomer is both almost inactive and more toxic than the racemate.
>
> For example, when administered orally to mice, zopiclone possesses a toxicity (LD50 [sic LD50]) in the region of 850 mg/kg, whereas the dextrorotatory isomer has a toxicity in the region of 1.5 g/kg and the laevorotatory isomer possesses an LD50 [sic LD50] of between 300 and 900 mg/kg.

Id. ¶ 59.

One noteworthy piece of evidence submitted in support of the applicants' argument was "data from a rat toxicity study conducted at a dose of 62.5 mg/kg." Id. ¶ 61. According to the patent applicants, at this dosage in rats, racemic zopiclone is more toxic than eszopiclone, and "racemic ZOPICLONE showed a statistically significant decrease in free T4 levels at 62.5 mg/kg/day, a dose four times lower than the dose at which a statistically significant decrease occurred for d-ZOPICLONE." Id. Based on this data, they asserted that "it is clear that d- ZOPICLONE has a significantly lower toxicity than racemic ZOPICLONE." Id.

Wockhardt asserts that the patent applicants intentionally failed to submit test results that contradicted the above assertions regarding the "unexpected property" of the claimed dextrorotatory isomer of zopiclone.

First, Wockhardt asserts that the applicants prevented the patent examiner from considering

data showing that the claimed dextrorotatory (+) isomer (i.e., zopiclone) exhibited greater toxicity that the levorotatory (-) isomer or the racemic mixture. Id. Wockhardt asserts that the applicants did so by mischaracterizing data relating to an "acute oral toxicity test in mice" that was supplied to the PTO. As a result, Wockhardt argues, the applicants intended to deceive the examiner with respect to alleged unexpected results of the claimed inventions.

Second, Wockhardt asserts that Plaintiff improperly failed to disclose a study entitled "Acute i.v. tox in Albino rats with zopiclone" ("the 1999 Rat Study"), which also purportedly contradicted the representations the applicants made regarding unexpected results.

Wockhardt asserts that the patent applicants' failure to disclosure the two above references was materially misleading, and done with the intent to deceive the PTO.

II. APPLICABLE LAW

A. INEQUITABLE CONDUCT

It is well settled that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [Patent] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." McKesson Info. Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897, 913 (Fed. Cir. 2007). A breach of this duty constitutes inequitable conduct, which subjects any resulting patent to nullification. To establish inequitable conduct, a party must show that the patent applicant, "with intent to mislead or deceive the examiner, fail[ed] to disclose material information or submit[ed] material false information to the PTO during prosecution." Id. Inequitable conduct, therefore, has two elements–materiality and intent.

Information is material "when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1297 (Fed. Cir. 2008). However, "[i]nformation concealed from the PTO may be material even though it would not invalidate the patent." Li Second Family Ltd. v. Toshiba Corp., 231 F.3d 1373, 1380 (Fed. Cir. 2000). An otherwise material reference is not material if it is merely cumulative to, or less relevant than, information already considered by the examiner. See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1577 (Fed. Cir. 1996); FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987).

To determine whether there is intent to deceive the examiner, courts look at all the facts surrounding an applicant's overall conduct to infer culpability because "[i]ntent rarely can be, and need not be, proven by direct evidence." Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364 (Fed. Cir. 2007). More than an omission of material information is necessary, "clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required." Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990).

Materiality and intent are separate elements of inequitable conduct, and must each be proven by clear and convincing evidence for a patent to be rendered unenforceable. Id. Nonetheless, the showing of intent can be proportionally less when balanced against high materiality. N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1987). Similarly, the showing of intent must be proportionally greater when balanced against low materiality. Id.

B. STANDARD OF REVIEW - FED. R. CIV. P. 12(b)(6)

In deciding a motion to dismiss pursuant to FED. R. CIV. P. 12(b)(6), all allegations in the complaint must be taken as true and viewed in the light most favorable to the plaintiff. See Warth

v. Seldin, 422 U.S. 490, 501 (1975); Trump Hotels & Casino Resorts, Inc., v. Mirage Resorts Inc., 140 F.3d 478, 483 (3d Cir.1998). If, after viewing the allegations in the complaint in the light most favorable to the plaintiff, it appears beyond doubt that no relief could be granted "under any set of facts which could prove consistent with the allegations," a court shall dismiss a complaint for failure to state a claim. Hishon v. King & Spalding, 467 U.S. 69, 73 (1984). In Bell Atlantic Corp. v. Twombly the Supreme Court clarified the Rule 12(b)(6) standard. 127 S.Ct. 1955 (2007). Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim, which would entitle him to relief." Twombly, at 1968 (citing Conley, 355 U.S. at 45-46). Instead, the Supreme Court instructed that "[f]actual allegations must be enough to raise a right to relief above the speculative level." Id. at 1965. Ultimately, the question is whether the claimant can prove a set of facts consistent with his or her allegations that will entitle him or her to relief, not whether that person will ultimately prevail. Semerenko v. Cendant Corp., 223 F.3d 165, 173 (3d Cir. 2000).

III. DISCUSSION

Wockhardt contends that Sepracor, through its agents charged with prosecuting the patents-in-issue, breached their duty of candor to the PTO by: **(A)** mischaracterizing data submitted to the PTO pertaining to an "acute oral toxicity test in mice," and by failing to disclose information that would have permitted the examiner to properly interpret such data; and **(B)** failing to disclose a "1999 Rat Study," the results of which allegedly contradict prior representations that the patent applicants made to the PTO.

A. ALLEGED MISCHARACTERIZATION OF DATA FROM THE ORAL TOXICITY STUDY

1. The Parties' Contentions

Wockhardt contends that the patent applicants breached their duty of candor to the PTO by allegedly mischaracterizing the data relating to an acute oral toxicity test in mice (the "oral toxicity study").

In February 2001, the patent applicants filed a Continued Prosecution Application "for the purpose of placing of record several items which are listed in the Information Disclosure Statement (IDS) filed concurrently herewith." Id. ¶ 63. Among the items submitted was a one-page summary data sheet from Sepracor's IND for Lunesta® presenting the results of an acute oral toxicity test in mice using racemic zopiclone and its isomers. Id. According to the patent applicants,

> [n]one of this cited information related to toxicity is believed to adversely affect patentability of the allowed claim, but is brought to the Patent and Trademark Office's attention out of an abundance of caution in view of prosecution of the parent, in which issues relating to the effects of (+) zopiclone vs. the racemate were considered. In particular, claim 6 was allowed in view of the showing that the (+) zopiclone isomer possesses unexpectedly lower toxicity than the racemate *under conditions of use*. Under the dosages considered, the racemate was found to have significant non-lethal thyrotoxicity, in comparison to the (+) isomer. **In the acute toxicity data submitted herewith, the results were generally comparable for the (+) isomer and the racemate**. However, one of ordinary skill in the art would clearly understand that the results obtained upon administration of the massive and lethal dosages employed in the acute toxicity testing are not in conflict with the test results submitted and discussed in the Bonnefoi and Doble Declarations of record, which, as noted above, were based upon dosages corresponding to expected conditions of use in humans.

Id. Wockhardt asserts that the emphasized portion of the quote above is false, and that the data in the one-page summary from Sepracor's IND shows that the data presented is not "generally comparable." Id. ¶ 64. In fact, Wockhardt asserts, the data in the one-page IND summary shows that the claimed (+) isomer exhibits a lower Median Lethal Dose, and is therefore more toxic than the

racemate—in direct contradiction of the data summary/arguments presented to the PTO. Id.[3]

Plaintiff responds that (i) Wockhardt's inequitable conduct affirmative defense/counterclaim has not been adequately plead, (ii) the allegedly mischaracterized toxicity study was actually presented to the examiner, so any mischaracterization thereof does not constitute inequitable conduct, (iii) the information contained in the oral toxicity study was irrelevant, and (iv) there is no evidence indicating that any Sepracor employee/agent knew the statement made with respect to the one-page summary was false at the time it was made.

2. Analysis

First, the Court agrees with Plaintiff that Defendants failed to meet the stringent pleading standard set forth by the Federal Circuit in Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1326 (Fed. Cir. Aug. 4, 2009) (noting that allegations of inequitable conduct must be pled with particularity under Fed. R. Civ. P. 9(b)).

Parties alleging inequitable conduct must describe the "specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO" and provide particular facts from which intent can be established. Id. Here, Wockhardt has generally referred to "the patent applicants" and "Sepracor" in its Amended Answer when discussing the materiality/intent of the alleged misrepresentation throughout its submission. See Doc. No. 140, ¶¶ 52-69 (failing to assert specific names of the individuals involved in the alleged inequitable conduct).[4] Although Wockhardt attempts to provide some degree of detail in its Opposition to Plaintiff's motion, see

[3] Wockhardt also asserts that the examiner had no way of knowing from the one-page IND summary that the more toxic (S)-isomer was the (+) isomer. Id.

[4] In fact, Wockhardt appears to have conceded that it was unable to describe the "who" aspect of Exergen in its pleadings. See Doc. No 176, at 20-21.

generally Doc. No 176, "[i]t is well-settled . . . that [a party] may not amend [its pleadings] through arguments in [its] brief." Francis v. Joint Force Headquarters Nat'l Guard, 2009 U.S. Dist. LEXIS 2755 (D.N.J. Jan. 12, 2009); see also Shanahan v. City of Chicago, 82 F.3d 776, 781 (7th Cir. 1996). Wockhardt has not met the exacting pleading requirements of Exergen.

Typically, when a party fails to plead claims or defenses with sufficient specificity, a court will freely grant leave to amend. Here, however, Wockhardt will not be permitted to Amend its affirmative defense/counterclaim **with respect to its arguments that the patent applicants failed to properly disclose the oral toxicity study**. For the reasons stated below, the Court finds that any amendment to the pleadings on this point would be futile, and therefore inappropriate. See In re Burlington Coat Factory Securities Litig., 114 F.3d 1410, 1434 (3d Cir. 1997).

The second reason Wockhardt's inequitable conduct claim must be dismissed is because the oral toxicity study results were before the examiner, and he was entitled to reach his own conclusions on the study. See Young v. Lumenis, Inc., 492 F.3d 1336, 1349 (Fed. Cir. 2007) ("When an examiner has the references to refer to during a patent examination, he is free to reach his own conclusion in the face of attorney argument, attempting to distinguish the claims from the prior art."); Bayer Schering Pharma AG v. Barr Labs., Inc., 2008 U.S. Dist. LEXIS 15917, at *151 (D.N.J. Mar. 3, 2008), aff'd, 575 F.3d 1341 (Fed. Cir. 2009) ("An applicant's arguments supporting its patent application do not constitute inequitable conduct when the examiner has the prior art before him throughout the prosecution and, despite the applicant's attempt to distinguish that prior art, [t]he examiner was free to reach his own conclusion regarding [the prior art].") (internal citations omitted). Therefore, any mischaracterization of the data would not rise to the level of inequitable conduct.

Wockhardt responds that, under the circumstances here, the examiner was not able to reach his own conclusion as to the test data—and that the applicants' mischaracterization of the data, therefore, constitutes inequitable conduct. Specifically, Wockhardt asserts that the examiner was not able to recognize that the patent applicants misconstrued the test results because the applicants did not indicate in the one-page summary whether the isomer was the (+) or (-) isomer, and instead referred to the covered isomers according to their (S) or (R) classifications only. Id. Accordingly, Wockhardt asserts, the examiner could not properly interpret the oral toxicity study data. However, between this document and other materials submitted to the PTO, the Court cannot agree that the patent applicants concealed material facts regarding the claimed/tested isomers' classification. See Doc. 179-6, at 4-5. Indeed, the examiner's assessment of the test results, as discussed infra, indicates that he was able to sufficiently consider the data and any impact it might have on the applicants' patent.

Third, and most important, the information that Wockhardt asserts was material to patentability—i.e., the allegedly mischaracterized data regarding the toxicity study—was considered to be irrelevant by the examiner. In the Notice of Allowance, the examiner stated that the test results had no impact on his view of the patentability of the invention because "**the test of Median Lethal Dose is a different test and reflects toxicity at a much higher dosage**." See Doc. No. 172-2, Ex. B. If, as the Notice of Allowance indicates, the S/R classification was irrelevant to the examiner, then Plaintiff's failure to specifically indicate the (+)/(-) classification of the claimed isomer cannot have been material. As such, Wockhardt cannot prevail on its inequitable conduct claim with respect

to this reference.[5]

Fourth, there is no evidence indicating that any individual with a duty of candor to the PTO believed that the statements regarding the oral toxicity study were false at the time they were made. Wockhardt attempts to plead the requisite intent by stating that Sepracor was aware of the above-discussed test data and failed to disclose it. In support of this assertion, Wockhardt points to a document that purportedly shows that the applicants were aware of the falsity of the statements they made in summarizing the test data. This document, however, was generated in December 2003, well after the time of patent application, and does not alone present facts from which this Court can infer that the applicants intended to deceive the PTO by not disclosing such information.

* * * * *

For the reasons stated, the Court will grant Sepracor's motion to dismiss Wockhardt's inequitable conduct claim/defense.

B. NON-DISCLOSURE OF A 1999 RAT STUDY

Wockhardt next asserts that the patent applicants were in possession of additional data that contradicted the data presented in the patent specifications and the Bonnefoi and Doble Declarations, but did not submit such data to the PTO. Id. ¶ 64.

During the time the patent applicants were prosecuting the family of applications leading to the patents-in-issue, Sepracor conducted, or caused to be conducted, a study entitled "Acute i.v. tox in Albino rats with zopiclone" ("the 1999 Rat Study"). Id. In the 1999 Rat Study, each of (+)-

[5] The Court notes that the applicants later (after issuance of the patent) explicitly informed the PTO that the oral toxicity study summary data sheet referred to the S[dextro]-isomer.

zopiclone ("eszopiclone" or "the S-isomer"), (-)-zopiclone ("the R-isomer") and racemic-zopiclone ("the RS-" or "the racemate") were administered to rats and the median lethal dose (MLD) was determined. Id. According to the summary of the 1999 Rat Study in Sepracor's NDA for Lunesta®, the MLD in male rats was lower (more toxic) for (+)-zopiclone (1-10 mg/kg) than for the racemate (25-50 mg/kg). Id. Wockhardt, then, asserts that this information contradicts the arguments and Declarations submitted to the PTO, wherein the applicants argued that the (+)-isomer has a lower toxicity than that of the racemate. Id.

First, Wockhardt's second basis for asserting inequitable conduct must fail for the threshold reason stated above with respect to the oral toxicity study: the Court finds that Wockhardt's pleadings with respect to the Rat Study are inadequate under Exergen. See page 10, supra. As with the first reference (i.e., the oral toxicity study discussed above), the Court must determine whether amendment of Wockhardt's inequitable conduct counterclaim/defense premised upon the nondisclosure of the 1999 Rat Study would be futile. See In re Burlington Coat Factory, 114 F.3d at 1434.

Plaintiff argues that amendment would be futile because: (i) Median Lethal Dose testing, as in the 1999 Rat Study, was irrelevant to patentability in this case, and (ii) **i.v.** toxicity data (as opposed to **oral** toxicity data), the variety of testing in the 1999 Rat Study, is irrelevant. This Court cannot make this determination on Plaintiff's motion to dismiss.

First, the Court agrees with Plaintiff that the examiner observed that "Median Lethal Dose" testing may not be relevant to patentability as such studies "reflect[] toxicity at a much higher dosage," and not at the intended use dosage. See Doc. 172-2, Ex. B. However, Wockhardt asserts that the dosages in the 1999 Rat Study are similar to the dosages used in the test that was actually

submitted to the PTO by the applicants. Accepting that statement as true, the Court cannot find that the1999 Rat Study results were entirely immaterial to the dosages covered by the patents. Accordingly, the Court cannot determine that the 1999 Rat Study would have been immaterial to the examiner in determining whether to grant Plaintiff's patents.

Second, Plaintiff's assertion that i.v. toxicity data cannot be fairly compared to oral toxicity data, whether accurate or not, is not a determination that this Court can make on the current record.

At this stage, the Court expresses no opinion as to the merits of Wockhardt's remaining argument in support of its inequitable conduct claim, and merely finds that a decision as to the claim cannot be rendered on this motion to dismiss. Accordingly, the Court will grant Wockhardt leave to amend its inequitable conduct counterclaim/defense with respect to the patent applicants' non-disclosure of the 1999 Rat Study results.

IV. CONCLUSION

For the reasons stated above, this Court finds that Wockhardt's claim of inequitable conduct based on Plaintiff's characterization of the oral toxicity studies is **dismissed with prejudice**, and Wockhardt's claim of inequitable conduct based upon Plaintiff's failure to disclose the 1999 Rat Study is **dismissed without prejudice**.

/s/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: June 7th, 2010
Original: Clerk's Office
cc: All Counsel of Record
The Honorable Mark Falk, U.S.M.J.
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